K133079

DEC 17 2013

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Submitter Information

510(k) Owner:	Alden Optical Laboratories, Inc. 6 Lancaster Pkwy Lancaster, NY 14086 USA
Contact Person:	Mr. Charley Creighton 716-937-9181 (office) 716-937-3303 (fax)
Consultant & Submission Correspondent:	Kevin Randall, Principal Consultant ComplianceAcuity, Inc. Golden, CO 80403 (303) 828-0844 (direct) (303) 828-0835 (fax) Email: info@complianceacuity.com
Date Summary Prepared:	September 27, 2013

II. Name of Device

Trade Name:	iO_2 (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Common/Usual Name:	Soft (hydrophilic) contact lens
Classification Name:	Lenses, Soft Contact, Daily Wear
USAN (generic name):	Mangofilcon A

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III. Device Description & Technological Characteristics

The iO_2 (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is available in spherical, multifocal, toric, and toric-multifocal designs. Specifically, the iO_2 Sphere, iO_2 Toric, ASTERA Multifocal iO_2, and ASTERA Multifocal Toric iO_2 models are hemispheric flexible shells of the following parameters:

	iO_2 Sphere	ASTERA Multifocal iO_2	iO_2 Toric	ASTERA Multifocal Toric iO_2
Diameter(s)	10.0 mm to 16.0 mm			
Center Thickness (Low Minus Lens)	0.07 mm dry			
Center Thickness (Plus Lens)	Up to 0.50 mm			
Base Curve(s)	6.5 mm - 9.9 mm			
Powers	-30.00 D to +30.00 D			
Cylinder Powers	Not Applicable (N/A)		Up to-10.00 D in steps of 0.25 D	
Axis	Not Applicable (N/A)		1° to 180°	
Add Powers	N/A	P1/ to +1.50 P2/ +1.75 to +2.25 P3/ +2.50 up	N/A	P1/ to +1.50 P2/ +1.75 to +2.25 P3/ +2.50 up

All iO_2 lenses are plasma treated in the dry state prior to initial hydration.

The lens material (mangofilcon A) is a non-ionic hydrophilic copolymer that consists of 51% mangofilcon A and 49% water by weight. Mangofilcon A is available clear (no tint) with or without a UV absorber to block a significant amount of the UV radiation occurring between 200 and 400 nm (UVA and UVB). Mangofilcon A is also available in Blue or Aqua visibility tints to assist with handling. Both colors are available with or without the UV absorber.

The physicochemical properties of iO_2 (mangofilcon A) Soft (hydrophilic) Contact Lenses for Daily Wear are tabulated at the top of the next page:

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iO_2 (mangofilcon A) Physicochemical Properties

Characteristic	Value
Dk	49 (Fatt Units @ 35°C)
REFRACTIVE INDEX	Dry: 1.470
	Hydrated: 1.413
SPECIFIC GRAVITY	Dry: 1.112
	Hydrated: 1.109
LINEAR EXPANSION RATIO	1.26
WATER CONTENT	49%
LIGHT TRANSMITTANCE	Clear: 96%T
	Tinted: >70%T
PLASMA TREATMENT REQUIRED	Yes
SHORE D HARDNESS (blank form)	≥ 83

IV. Indications for Use

The **iO_2 Sphere (mangofilcon A) Soft (hydrophilic) Contact Lens** is indicated for the correction of myopia and hyperopia in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +30.00 to -30.00 D.

The **ASTERA Multifocal iO_2 (mangofilcon A) Soft (hydrophilic) Contact Lens** is indicated for the correction of presbyopia in myopic and hyperopic eyes in aphakic or non-aphakic patients with non-diseased eyes who exhibit no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +30.00 to -30.00 D and have near add requirements up to 3.25 D.

The **iO_2Toric (mangofilcon A) Soft (hydrophilic) Contact Lens** is indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or non-aphakic persons with non diseased eyes in a spherical power range of +30.00 to
-30.00 D and a cylinder power range up to -10.0D.

The **ASTERA Multifocal Toric iO_2 (mangofilcon A) Soft (hydrophilic) Contact Lens** is indicated for the correction of presbyopia in myopic, hyperopic and astigmatic aphakic or non-aphakic patients with non-diseased eyes in a spherical power range of +30.00 to -30.00 D, a cylinder power range up to -10.00 D and an add requirement up to 3.25 D.

iO_2 lenses may be disinfected using chemical (not heat) disinfecting systems.

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V. Comparison to Legally Marketed Predicate

PROPERTY	iO_2 (mangofilcon A) (subject device)	LSH (mangofilcon A) (predicate device)
Marketing Status	Not Yet Cleared	K120756
USAN	Mangofilcon A	Mangofilcon A
Device Class	II	II
FDA Product Code	LPL	LPL
Regulation	21 CFR 886.5925	21 CFR 886.5925
Intended Use	Same as predicate LSH	Same as subject iO_2
Manufacturing Method	Lathe-cut	Lathe-cut
Plasma Treatment?	Yes	Yes
Water Content	49%	49%
Oxygen Transmissibility	49 (ISO/Fatt)	49 (ISO/Fatt)
Refractive Index	Dry: 1.470	Dry: 1.470
	Hydrated: 1.413	Hydrated: 1.413
Specific Gravity	Dry: 1.112	Dry: 1.112
	Hydrated: 1.109	Hydrated: 1.109
Shore D Hardness	≥ 83	≥ 83
Tensile Strength	3.07 M Pa	3.07 M Pa
Elongation at Break	470%	470%
Light Transmittance	Clear: 96%T	Clear: 96%T
	Tinted: >70%T	Tinted: >70%T

VI. Summary of Non-Clinical Performance Data

A combination of relevant non-clinical analysis and testing has been assured, including:

• Chemical composition of finished lenses	• Color and light transmittance
• Purity of initial monomers	• Refractive index
• Shelf Life	• Water content
• Leachability of Residual Monomers	• Oxygen transmissibility
• Leachability of Color Additives / UV Absorber	• Specific gravity
• Biocompatibility testing	• Mechanical Testing & Hardness
• Preservative Uptake and Release	• Lens/Solution Compatibility

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VIII. Conclusions Drawn

It is the conviction of Alden Optical Laboratories that the information and data submitted in this premarket notification substantiate our ability to manufacture a contact lens with a safety and effectiveness profile that is substantially equivalent to the predicate device, and that *does not raise* different questions of safety and effectiveness. Based on these facts, Alden therefore concludes that the subject device is as safe and as effective, that is, "substantially equivalent" to, the predicate pursuant to section 513(i) of the Act.

END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 19, 2014

Alden Optical Laboratories, Inc.
% Mr. Kevin Randall, RAC
ComplianceAcuity, Inc.
16576 W. 53rd Way
Golden, CO 80403

Re: K133079
Trade Name: iO_2 (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: II
Product Code: LPL
Dated: November 5, 2013
Received: November 6, 2013

Dear Mr. Randall:

This letter corrects our substantially equivalent letter of December 17, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133079

Device Name: iO_2 (mangofilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joseph C. Hutter -S
2013.12.13 13:18:08 -05'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose
and Throat Devices

510(k) Number K133079